

## **REMARKS**

The above amendments and these remarks are responsive to the final Office action dated September 5, 2007, and support the accompanying Request for Continued Examination as a submission under 37 C.F.R. § 1.114(c). Claims 5–9, 11, 13–15, 17–26, 28, and 31–40 are pending in the application. In the final Office action, the Examiner rejected each of the pending claims as follows:

- Claims 5–9, 11, 13–15, 19, 21–25, 35–38, and 40 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,693,055 to Zahiri et al. (“Zahiri”);
- Claim 26 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Zahiri;
- Claims 34 and 39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Zahiri in view of U.S. Patent No. 5,743,912 to Lahille et al. (“Lahille”);
- Claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Zahiri in view of U.S. Patent No. 6,048,344 to Schenk (“Schenk”); and
- Claims 17 and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Zahiri in view of U.S. Patent No. 5,470,334 to Ross et al. (“Ross”).

Applicants traverse the rejections, contending that all of the claims are patentable over the cited references. Nevertheless, to expedite the issuance of a patent, and to more particularly point out and distinctly claim aspects of the invention that applicants would like to patent now, applicants have amended claims 5, 9, 11, 13, 15, 21–24, 28, 34, 35, and 39. However, applicants reserve the right to pursue any of the amended claims, in original or amended form, at a later time. Furthermore, applicants have presented arguments showing that all of the pending claims are patentable over the cited references, taken alone or in combination. Accordingly, applicants respectfully request

reconsideration of the application in view of the amendments above and the remarks below, and prompt issuance of a Notice of Allowance covering all of the pending claims.

***I. Request for Continued Examination***

Applicants are submitting herewith a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114. This Request complies with the requirements of 37 C.F.R. § 1.114 as follows:

- (i) Prosecution in the application is closed, since the latest Office action was a final Office action under 37 C.F.R. § 1.113.
- (ii) The Request is accompanied by a submission as set forth at 37 C.F.R. § 1.114(c), specifically, the amendments and remarks set forth herein.
- (iii) The Request is accompanied by the fee set forth at 37 C.F.R. § 1.17(e).

Accordingly, applicants respectfully request grant of their Request for Continued Examination.

***II. Claim Amendments***

The present communication amends claims 5, 9, 11, 13, 15, 21–24, 28, 34, 35, and 39, by introducing one or more of only three changes into each claim. First, each of claims 5, 9, 11, 13, 15, 21–24, 28, and 34 has been amended to replace “ledge structure” with “shoulder.” These terms are used interchangeably in the application and are intended to have the same meaning. Accordingly, applicants have adopted the term “shoulder” for use throughout the claims to improve clarity. Second, each of the independent claims, namely, claims 5, 21, 28, and 35, has been amended to recite that “a portion of the bone near the head is engaged by two or more of the shoulders.” In contrast, before amendment, each of the independent claims recited engagement by one or more of

the shoulders/ledge structures. Exemplary support for this amendment to the independent claims is provided by the application, for example, on page 4, lines 4 and 5; on page 5, lines 11-13; and in Figures 1 and 2, among others. Third, claims 34 and 39 have been reworded to recite shoulders that “flare generally toward the direction of advancement into bone.” The term “flare” replaces the phrase “slope radially outward,” in a further effort to improve clarity and be more concise.

### **III. Claim Rejections – 35 U.S.C. §§ 102 and 103**

The Examiner rejected each of the pending claims as being anticipated or obvious. Applicants traverse the rejections, contending that the cited references, taken alone or in combination, do not disclose, teach, or suggest every element of any of the rejected claims. Nevertheless, for the reasons set forth above, applicants have amended each of the independent claims, namely, claims 5, 21, 28, and 35, and also have amended dependent claims 9, 11, 13, 15, 22–24, 34, and 39. Each of the independent claims, and all of the claims depending therefrom, are patentable for at least the reasons set forth below.

#### **A. Claims 5–9, 11, 13–15, 17–20, and 34**

##### **i. Claim 5**

Independent claim 5, as amended, reads as follows:

5. (Currently Amended) A method of compressing a bone, comprising:

selecting a bone screw including

a shank including a thread disposed externally for threaded engagement with bone, the shank defining a long axis and a direction of advancement into bone, and

a head connected to the shank and defining a plurality of **shoulders**  
~~ledge structures~~ disposed at spaced positions generally along the head, each

shoulder ledge structure facing generally toward the direction of advancement and extending partially or completely around the head to define a respective plane disposed orthogonally to the long axis; and

installing the bone screw in a bone such that a portion of the bone near the head is engaged by two [[one]] or more of the shoulders ledge structures and is urged toward a portion of the bone near the shank.

In the Office action, claim 5 was rejected as being anticipated by Zahiri. However, Zahiri does not disclose, teach, or suggest every element of amended claim 5. For example, Zahiri does not disclose, teach, or suggest “installing the bone screw in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders.”

Zahiri relates to an internal bone fixation device for fixation at an odd angle, that is, obliquely to the long axis of the bone. Figure 2 of Zahiri, which is reproduced here to facilitate review, presents an exploded view of an embodiment of an odd angle fixation device 10. The device has two components, namely, an elongated lag screw 12 and a rectangular guide plate 14. Screw 12 has a proximal portion 16 connected to a middle shaft 18 and a distal threaded portion 20. Proximal portion 16 includes a head 22 disposed proximally to a shoulder flange 24.

Figure 4 of Zahiri, which is reproduced here to facilitate review, presents a sectional view of guide plate 14 taken longitudinally. Guide plate 14 includes a barrel portion 38 projecting from the inner surface of a plate-shaped portion of the guide plate. The barrel portion defines a bore 36 of two distinct diameters to create a smaller distal opening 42 and a larger proximal opening 46, which are separated by an inner flange 50.

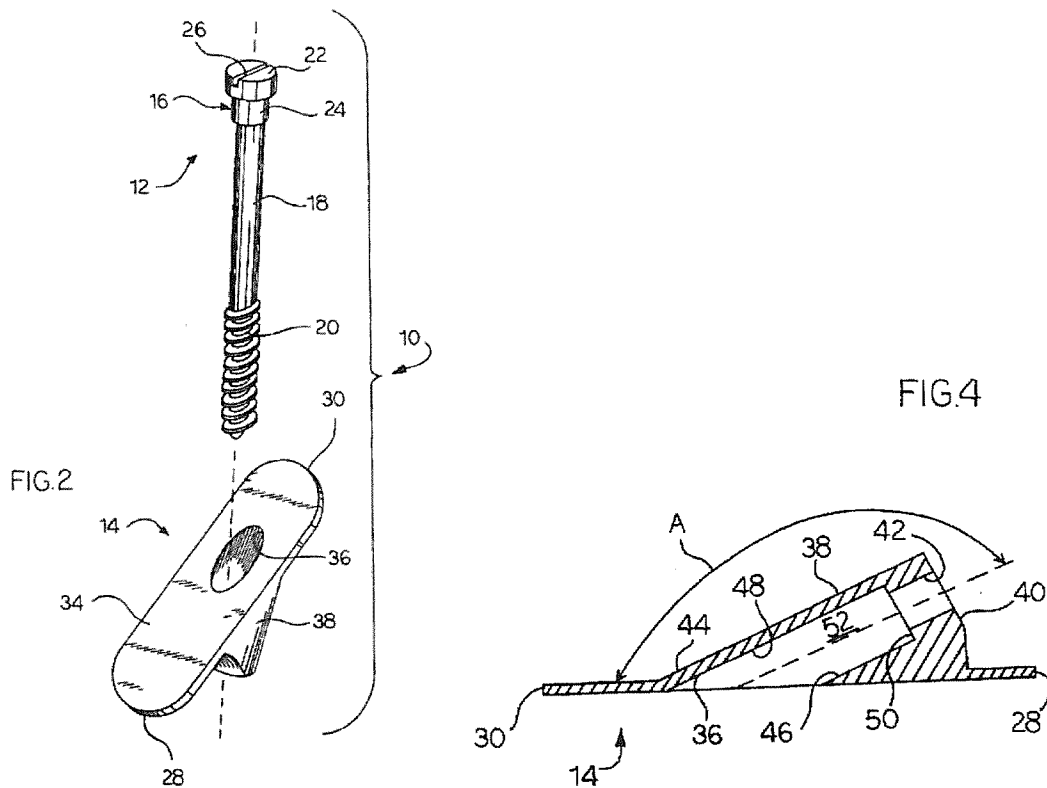
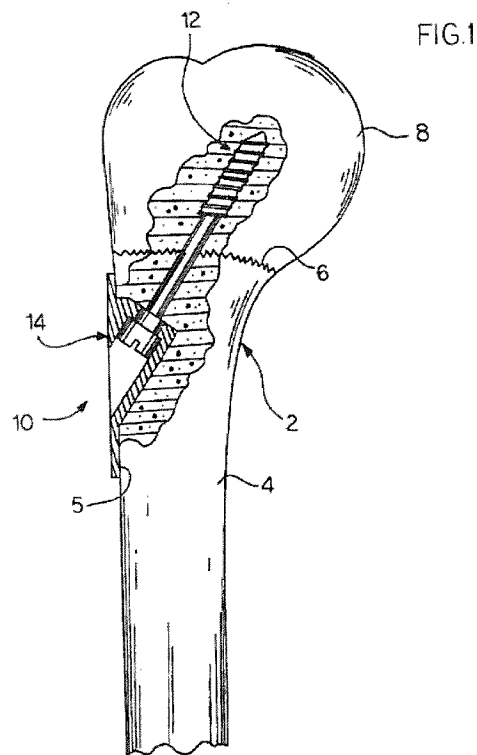


Figure 1 of Zahiri, which is reproduced here to facilitate review, presents a sectional view of internal fixation device 10 installed in a bone having a fracture line 6. Screw 12 extends through the hole (36) of guide plate 14 and into the bone (also see Figure 4). Both the head (22) and the shoulder flange (24) of the screw are disposed in respective larger and smaller diameter openings (46 and 42) of the guide plate (also see Figure 4). Significantly, the leading end of the shoulder flange (24) is the only surface of the head or shoulder flange that is apposed to and/or in contact with bone. In particular, all of the head (22) and the lateral surface of the shoulder flange (24) are separated from bone by the guide plate.



The Examiner, in rejecting claim 5, asserted that head 24 and shoulder flange 22 of screw 12 provide a plurality of spaced shoulders. However, if the leading ends of head 24 and shoulder flange 22 are construed as shoulders, only one shoulder can

engage bone when fixation device 10 is installed. In contrast, amended claim 5 recites “installing the bone screw in a bone such that a portion of the bone near the head is engaged by two or more of the shoulders.” Zahiri thus does not disclose, teach, or suggest every element of claim 5.

Applicants also contend that it would not have been obvious to modify Zahiri such that bone is engaged by two or more shoulders, for at least two reasons.

First, applicants submit that contact, if any, between shoulder flange 22 of screw 12 and bone is not intended to play a primary role in compression, because proximal portion 16 of screw 12 bears primarily against inner flange 50 of guide plate 14 to transmit a compressive force to the bone over an expanded surface area via the guide plate. Accordingly, one of skill in the art would have had no motivation to increase the amount of contact between proximal portion 16 and bone by adding a second shoulder flange that protrudes into bone from the inner surface of guide plate 14 for engagement with bone. In particular, a second shoulder flange would have been expected to provide no substantial improvement in the ability of proximal portion 16 to bear against the guide plate and to compress bone.

Second, Zahiri teaches away from increasing the amount of contact between proximal portion 16 of screw 12 and bone. In particular, the reference teaches that concentrating the compression force on bone, as would have been expected to occur by installing the screw without the guide plate, is undesirable because the concentrated contact is not healthy for the bone and does not offer the best mechanical advantage. For example, Zahiri states that “the guide plate is designed to dissipate all the compression forces of the odd angle internal fixation device that are applied against the

bone cortex, and practically reduces the forces to an easily tolerable level by the bone cortex” (col. 4, lines 24–28). Zahiri further states that with dissipation of forces by the guide plate “the bone cortex remains healthy and intact which results in mechanical advantage not provided by any screw design in the prior art” (col. 4, lines 31-34). In other words, based on the teach-away of Zahiri, one of skill in the art would have been motivated not to increase the amount of contact between proximal portion 16 of screw 12 and bone. Accordingly, with the teach-away of Zahiri, one of skill in the art would have been motivated not to add a second shoulder to screw 12 that protrudes from the inner face of the guide plate and would have been motivated not to use screw 12 without guide plate 14, because both of these modifications would have diminished or removed the ability of the guide plate to dissipate compression forces exerted on the bone cortex and thus would have diminished or destroyed the mechanical advantage provided by the guide plate. Zahiri further teaches away from the use of screw 12 without guide plate 14 by stating in the Background of the Invention that “use of screws alone does not provide sufficient temporary mechanical fixation at the fracture site to allow the normal use of the upper or lower extremity for normal daily activities while the fracture is healing” (col. 1, lines 34–37).

In summary, Zahiri does not disclose, teach, or suggest every element of amended claim 5 and it would not have been obvious to modify Zahiri to achieve the claimed invention. The other references cited in the Office action, namely, Lahille, Schenk, and Ross, taken alone or in combination, do not correct the defect in Zahiri. Accordingly, claim 5 should be allowed. In addition, claims 6–9, 11, 13–15, 17–20, and



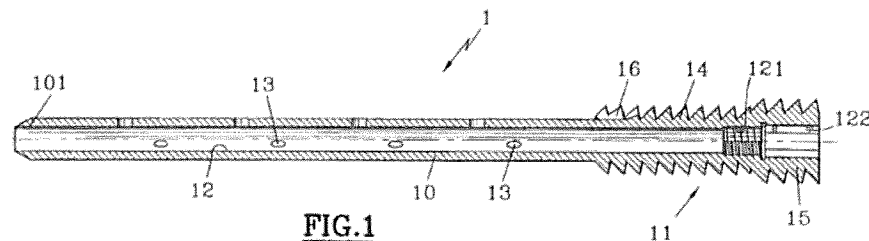
34, which depend from claim 5, also should be allowed for at least the same reasons as claim 5.

*ii. Claim 34*

Some or all of the dependent claims further distinguish the method of claim 5 patentably from the cited references. For example, claim 34 is discussed here.

The Examiner rejected claim 34 in the final Office action over a combination of Zahiri and Lahille. Applicants traverse the rejection because the cited references, taken alone or in combination, do not disclose, teach, or suggest every element of claim 34, prior to entry of the present claim amendments. However, the present communication amends claim 34 to improve clarity. Claim 34, as amended, now recites “wherein the step of selecting a bone screw includes a step of selecting a bone screw in which one or more of the shoulders flare generally toward the direction of advancement into bone.”

The Examiner relied on Lahille for allegedly disclosing a sloped/flared shoulder. Lahille involves an implant for the upper femur. Figure 1 of the reference, which is reproduced here to facilitate review, illustrates a longitudinal sectional view of a body 1 of the implant. The body includes a leading tubular portion 10 and a trailing anchor portion 11 with external threads 14, 15 of distinct diameter.



The Examiner referred to element 14 (external thread 14) of Lahille in rejecting claim 34. External thread 14 is formed by a ridge. The ridge, as illustrated in Figure 1 of Lahille above, provides a helical leading surface that (1) faces generally toward and (2) flares generally away from the direction of advancement (i.e., in shorthand form (1) toward and (2) away). The ridge also provides a helical trailing surface that (1) faces generally away from, and either does not flare or (2) flares generally toward the direction of advancement (i.e., (1) away and (2) toward). Each shoulder of claim 34 faces and flares generally toward the direction of advancement into bone (i.e., (1) toward and (2) toward). Accordingly, neither the leading nor the trailing helical surface of thread 14 faces and flares in the direction recited by claim 34. Zahiri, Schenk, and Ross, taken alone or in combination, do not correct this defect in Lahille. The cited references thus do not disclose, teach, or suggest every element of claim 34. Therefore, claim 34 should be allowed not only for depending from independent claim 5 but also for further distinguishing the claimed invention of claim 5 from the cited references.

*B. Claims 21–26, 28, 31–33, and 35–40*

Independent claims 21, 28, and 35 each recite a step of installing or advancing “such that a portion of the bone near the head is engaged by two or more of the shoulders.” Accordingly, each of claims 21, 28, and 35 should be allowed for at least the same reasons as those presented above for claim 5. In addition, claims 22–26, 31–33, and 36–40 also should be allowed for at least the same reasons as claims 21, 28, and 35. Claim 39, which is similar to claim 34, also should be allowed not only for depending from independent claim 35 but also for the same additional reasons as claim 34.

**IV. Conclusion**

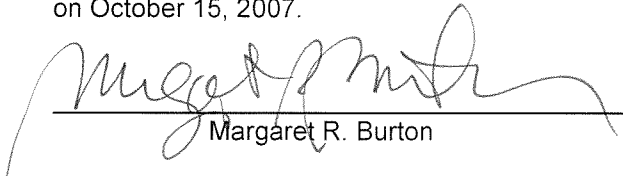
Applicants believe that each of the pending claims is patentable over the cited references. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowance covering all of the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record, or his associate, Stan Hollenberg (Reg. No. 47,658), both at (503) 224-6655.

Respectfully submitted,

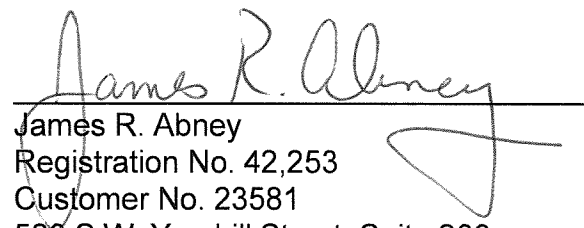
KOLISCH HARTWELL, P.C.

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